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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,622	01/14/2005	Takeshi Hagio	59150-8030	2017

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PERKINS COIE LLP
P.O. BOX 1208
SEATTLE, WA 98111-1208

EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,622	HAGIO ET AL.	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,8-27,29-48 and 71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,8-27,29-48 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 9, 2008 has been entered.

Claims 1, 4, 6, 8-27, 29-48, and 71 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is indefinite since it depends from a canceled claim, claim 7. Thus, claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph. For examination purposes, claims 8 and 9 each will be read as the method according to claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 8-27, 29-48, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over "US `212" (US 2005/0032212).

US `212 discloses cells having a cell wall may be permeabilized by a pressurization/depressurization process wherein depressurisation causes bubbles to form within the structure of a cell wall, causing the cell membrane to rupture at localized points (page 2, paragraph [0030]). The holes formed are transient and remain open for a sufficient time to allow the influx of macromolecules such as DNA and/or RNA into the cell (page 3, paragraph [0033]). The US `212 method may be combined with prior art methods, including electroporation, in order to further increase the efficiency of the method (page 2, paragraph [0017]). It is noted that the plant cells that may be treated included those recited in instant claims 8-22, 30-42 (page 5, paragraph [0061] and claim 23. Furthermore, following the method, the cells may be differentiated, grown, and/or multiplied (page 14, paragraph [0272]).

US `212 differs from the claimed method in that it does not teach that for depressurization, the pressure is reduced by about 0.096 MPa from the atmospheric pressure. Nevertheless, the selection of a specific suitable pressure, including that claimed would have been an obvious matter of optimization of a result-effective parameter on the part of the artisan of ordinary skill.

US `212 also differs from the claimed method in that it does not teach that it is practiced on each and every cell type recited in claims 23-26, 43-46, and 48. However, there would have been a reasonable expectation of success in transferring nucleic acids into cells of plants of the types recited in the instant claims to yield the predictable result of producing these plants. Moreover, US `212 indicates that "The present invention may be used for transformation of any plant species…" (page 5, paragraph [0061]).

A holding of obviousness is clearly required.

Claims 1, 4, 8-27, 29-48, and 71 rejected under 35 U.S.C. 103(a) as being unpatentable over "US `212" (US 2005/0032212) as applied to claims 1, 4, 8-27, 29-48, and 71 above, and further in view of Dev et al. (US 5,859,327).

As discussed above, US `212 renders claims 1, 4, 8-27, 29-48, and 71 obvious. However, they do not expressly disclose the voltage pulse applied for electroporation as recited in instant claim 6.

Dev et al. teaches "a method for producing a genetically modified plant by introducing a polynucleotide to an intact plant or plant cell(s) via electroporation, in the absence of cell wall-degrading enzymes" (abstract). The "plant cell" may be an intact cell of a seed (column 4, lines

15-17), wherein the recitation "intact" signifies that the cell wall is undamaged or untreated (column 4, lines 20-22). The method can be applied to monocotyledonous plants such as corn, wheat, rice, and dicotyledonous plants such as tomato, rapeseed, soybeans, and cabbage (column 6, lines 15-25). Moreover, Dev et al. indicates that "one of skill in the art could determine the appropriate parameters for the leaf type used" (column 8, lines 62-63). For instance, a voltage of 40-50 V/cm for electroporation, which is within the range recited in instant claim 6, is deemed suitable for "soft and thin" leaves (column 8, lines 63-65).

At the time the invention was made it would have been obvious to have applied electroporation described in Dev et al. as the electroporation step described in US `212. One of ordinary skill in the art would have been motivated to do this since electroporation assists in the introduction of genetic material to plant cells, as demonstrated in Dev et al. Moreover, it would have been obvious to one of ordinary skill in the art to apply electroporation as taught in Dev et al., to improve the genetic transfection method of Rickwood for the predictable result of introducing a substance into plant cells. The selection of a specific suitable voltage pulse and voltage pulse application directions, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly since Dev et al. demonstrates that the skilled artisan would determine the appropriate parameters for the leaf type used, and Dev et al. noted teaches that electroporation applied at a voltage of 40-50 V/cm, which is within the range recited in instant claim 6, is deemed suitable the introduction of a polynucleotide to "soft and thin" leaves.

A holding of obviousness is clearly required.

Claims 1, 4, 6, 8-27, 29-48, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rickwood (WO 01/05994, listed on IDS) in view of Dev et al. (US 5,859,327).

Rickwood discloses a method of introducing a substance into a cell wherein bubbles containing gas are generated in a liquid medium comprising the cell, and the bubble interacts with the cell to form a hole in the surface of the cell (page 2, last paragraph through page 3, first paragraph). The substance that can be introduced into a cell can be a nucleic acid (page 8, last paragraph). Transfection of the cells occurs at pressure below and above atmospheric pressure, such as a pressure of from $1x10^4$ Pa to atmospheric pressure (page 6, last paragraph). Thus, the cell is subjected to depressurization. Finally, the Rickwood method can be performed on plant cells (page 9, first paragraph).

Rickwood also differs from the claimed invention in that it does not expressly disclose that the cell and nucleic acid are placed under conditions to induce electroporation, such as the application of a voltage pulse of 10 V/cm to 200 V/cm in at least two directions. Moreover, Rickwood does not expressly disclose that the plant cells treated are of the types recited in instant claims 10-26 wherein the steps can be performed on a seed, and that the treated plant cell differentiates/grows/multiplies and/or yields a plant which may not contain a somaclonal variation.

Dev et al. teaches "a method for producing a genetically modified plant by introducing a polynucleotide to an intact plant or plant cell(s) via electroporation, in the absence of cell wall-degrading enzymes" (abstract). The "plant cell" may be an intact cell of a seed (column 4, lines 15-17), wherein the recitation "intact" signifies that the cell wall is undamaged or untreated (column 4, lines 20-22). The method can be applied to monocotyledonous plants such as corn,

wheat, rice, and dicotyledonous plants such as tomato, rapeseed, soybeans, and cabbage (column 6, lines 15-25). Moreover, Dev et al. indicates that "one of skill in the art could determine the appropriate parameters for the leaf type used" (column 8, lines 62-63). For instance, a voltage of 40-50 V/cm for electroporation, which is within the range recited in instant claim 6, is deemed suitable for "soft and thin" leaves (column 8, lines 63-65).

At the time the invention was made it would have been obvious to have applied electroporation in addition to the steps recited in Rickwood. One of ordinary skill in the art would have been motivated to do this since electroporation assists in the introduction of genetic material to plant cells, as demonstrated in Dev et al. Moreover, it would have been obvious to one of ordinary skill in the art to apply electroporation as taught in Dev et al., to improve the genetic transfection method of Rickwood for the predictable result of introducing a substance into plant cells. The selection of a specific suitable voltage pulse and voltage pulse application directions, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly since Dev et al. demonstrates that the skilled artisan would determine the appropriate parameters for the leaf type used, and Dev et al. noted teaches that electroporation applied at a voltage of 40-50 V/cm, which is within the range recited in instant claim 6, is deemed suitable the introduction of a polynucleotide to "soft and thin" leaves.

Additionally, there would have been a reasonable expectation of success in transferring nucleic acids into cells of plants of the types recited in the instant claims and the Dev reference to yield the predictable result of producing these plants.

Though Rickwood does not expressly disclose that the depressurization step is performed under a pressure reduced by about 0.096 MPa from the atmospheric pressure, the selection of a

specific suitable pressure, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill. Moreover, in reference to pressure conditions for transfection, Rickwood indicates that "Transfection can be carried out under widely varying conditions" (page 6, last paragraph).

Thus, a holding of obviousness is clearly required.

Claims 1, 4, 6, 8-27, 29-48, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmukler (US 5,173,158) in view of Gutierrez-Armenta et al. (US 2002/0046416) and Dev et al.

Schmukler teaches a method of electroporation wherein cells are trapped into pores in a film with diameters smaller than the diameters of the cells, and an electric field is applied to cause electroporation of the trapped cells (column 1, line 60 through column 2, line 3). The cells can be trapped into the pores by pressure such as hydrostatic pressure head from a regulated pressure source or a vacuum source (column 3, lines 20-26). Clearly the pressure applied to the cells must be different from atmospheric pressure. Thereafter, a low voltage pulse is applied which causes electroporation of the cells (column 3, lines 27-34). It is noted that "when the pressure gradient across the film is negative, or decreases from a positive value, the trapped first type of cells will pull in material, such as genetic material (DNA)..." from a portion of the apparatus used to perform the Schmukler invention (column 3, lines 44-47). Thus, the cells are exposed to depressurization.

Schmukler differs from the claimed invention in that it does not expressly disclose that the depressurization step is performed under a pressure reduced by about 0.096 MPa from the

atmospheric pressure, as required by claims 1 and 27. Nevertheless, the selection of a specific suitable pressure, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly since Schmukler teaches regulation of pressure applied (column 3, lines 20-26).

Furthermore, Schmukler differs from the claimed invention in that it does not expressly disclose that the cell treated is a plant cell of the types recited in instant claims 10-26 wherein the steps can be performed on a seed, and that the treated plant cell differentiates/grows/multiplies and/or yields a plant which may not contain a somaclonal variation. Moreover, there is no disclosure in Schmukler that the voltage pulse applied to the cell is of 10 V/cm to 200 V/cm, which is applied to the cell and the nucleic acid in at least two directions.

Gutierrez-Armenta et al. discloses that cell growth may be controlled by administering DNA to a cell, and that the DNA may be administered by electroporation of plant seed cells with DNA (page 2, paragraph [0015]).

Dev et al. teaches "a method for producing a genetically modified plant by introducing a polynucleotide to an intact plant or plant cell(s) via electroporation, in the absence of cell wall-degrading enzymes" (abstract). The "plant cell" may be an intact cell of a seed (column 4, lines 15-17), wherein the recitation "intact" signifies that the cell wall is undamaged or untreated (column 4, lines 20-22). The method can be applied to monocotyledonous plants such as corn, wheat, rice, and dicotyledonous plants such as tomato, rapeseed, soybeans, and cabbage (column 6, lines 15-25). Moreover, Dev et al. indicates that "one of skill in the art could determine the appropriate parameters for the leaf type used" (column 8, lines 62-63). For instance, a voltage of

40-50 V/cm for electroporation, which is within the range recited in instant claim 6, is deemed suitable for "soft and thin" leaves (column 8, lines 63-65).

At the time the invention was made, it would have been obvious to have practiced the invention on plant cells, which can be contained in seeds, to produce plants which may not contain a somaclonal variation. One of ordinary skill in the art would have been motivated to do this since electroporation has been found to be suitable for administering DNA to plant seed cells, and therefore, there would have been a reasonable expectation of success in transferring nucleic acid into plant cells to produce a plant by the methods of Schmukler which uses electroporation for nucleic acid transfer into cells. Additionally, there would have been a reasonable expectation of success in transferring nucleic acids into cells of plants of the types recited in the instant claims to yield the predictable result of producing these plants.

Also, the selection of a specific suitable voltage pulse and voltage pulse application directions, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly since Schmukler teaches regulation of pressure applied (column 3, lines 20-26). Also, Dev et al. demonstrates that the skilled artisan would determine the appropriate parameters for the leaf type used, and Dev et al. teaches that electroporation applied at a voltage of 40-50 V/cm, which is within the range recited in instant claim 6, is deemed suitable the introduction of a polynucleotide to "soft and thin" leaves. Moreover, Dev et al. also provides further support for administering DNA into cells of plants of the types recited in the instant claims by electroporation.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed October 9, 2008, have been fully considered but they are not persuasive. With respect to Rickwood, it is respectfully noted that the pressure is rendered obvious. It would have been obvious to have varied a result-effective parameter in practicing the Richwood invention. Furthermore, though Rickwood indicates that it is preferable to practice the invention with protoplasts, plant cells in general are indicated in Rickwood as being suitable. Thus, the Rickwood invention would have been worked with cells having an intact cell wall.

With respect to Schmukler, the applicant asserts that it is in reference to animal cells rather than plant cells. However, there is no recitation in Schmukler that plant cells are prohibited, nor does the applicant provide reasons for why the Schmukler invention is not suitable for practicing on plant cells. The cells are indeed held under the negative pressure created by the negative pressure gradient.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef